FROM: FOLEY & LARDNER

FAX NO.: 202-945-6173

Dec. 08 2000 03:21PM P1

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U.S. Patent and Trademark Office	(703) 305 9284	(703) 308 6916
Petitions Branch Attn: Karin Tyson		

In re Interim Patent Term Extension of U.S. Patent No. 4,373,527

Patentee: Robert E. Fischell

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

From: Stephen B. Macbius

Sender's Direct Dial: 202 672 5569

Date: December 8, 2000

Client/Matter No: 047711/0100

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Assistant to Stephen B. Maebius

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

In re INTERIM PATENT TERM EXTENSION OF U.S. Patent No. 4,373,527

Patentee:

Robert E. FISCHELL

Assignee:

The Johns Hopkins University

Issue Date:

February 15, 1983

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EIGHTH STATUS INQUIRY

PETITIONS OFFICE

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Patentee filed a Status Inquiry on October 13 and 27, November 3, 10, 17, 24 and December 1, 2000, relating to the above-captioned interim extension application. A Request for Reconsideration of Notice of Final Determination of Ineligibility was filed in the U.S. Patent Office on May 8, 2000. The U.S. Patent Office indicated that it is trying to get a response from the FDA to a letter dated March 27, 2000 (copy enclosed), from Ms. Karyn Tyson of the U.S. Patent Office to Mr. David Read of the FDA, so that it can decide how to respond to the Request for Reconsideration. It has more than been 7 months since that letter was sent.

On October 13 and 27, November 3, 10, 17 and 24, and December 1 2000, the patentee filed a status inquiry with the U.S. Patent Office with a copy to Mr. Read at the FDA. On October 19, 2000, the undersigned received a phone call from Ms. Claudia Grillo of the FDA, who indicated that the FDA is in the process of preparing a response to the Patent Office's March 27th letter, and that a response should be complete within a couple of weeks. The patentee hereby requests a status report as to the preparation of the FDA's response.

The patentee is required to file a renewed application for interim extension during a period that starts 60 days before the first year interim extension expires (i.e., such renewed application would need to be filed around December 15, 2000), but in this case, patentee has not yet even been granted the first extension, and the first-year period is drawing to a close.

Respectfully submitted,

Stephen B. Maebius
Attorney for Applicant

Registration No. 35,264

Hec. 8, 2000 Date

FOLEY & LARDNER 3000 K Street, N.W., Suite 500 Washington, D.C. 20007-5109 Telephone: (202) 672-5569

cc: Mr. David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, Maryland 20852



MAR 27 2000

UNITED STAN DEPARTMENT OF COMMERCE Patent and Tredemark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Weshington, D.C. 20231

David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

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Dear Mr. Read:

PETITIONS OFFICE

The attached application for interim patent term extension of U.S. Patent No. 4,373,527 was filed on January 28, 2000, under 35 U.S.C. § 156(d)(5).

The assistance of your Office is requested in confirming that the product identified in the application, Minimed 2007, is subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g)(3)(B)(ii).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156(d)(5) only if an application under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted prior to January 28, 2000 for the product Minimed 2007.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson

Senior Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

cc:

Francis A. Cooch
Office of Patent Counsel
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11100 Johns Hopkins Road/Laurel MD 20723-6099

kt